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EXAMINER	
HILL, KEVIN KAI	

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1633	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/540,759	GREEN ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-44* is/are pending in the application.

4a) Of the above claim(s) *13-18,24-27 and 29-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,19-23 and 28* is/are rejected.

7)☒ Claim(s) *3, 7 and 20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

1. Applicant's response to the Requirement for Restriction, filed on March 26, 2007 is acknowledged.

Applicant has elected the invention of Group I, Group I, Claims 1-12, 19-23 and 28, drawn to an isolated polynucleotide encoding a multifunctional Germacrene-D synthase, wherein the synthase comprises an amino acid sequence with at least 60% similarity to SEQ ID NO:2, and a genetic construct comprising said polynucleotide.

Within Group I, Applicant has elected the compound created as a result of a polypeptide acitivity species "i", Germacrene-D. However, in light of the specification (pg 35, lines 16-24), the Examiner has withdrawn the species election requirement, as the polypeptide of SEQ ID NO:2, encoded by the polynucleotide of SEQ ID NO:1 inherently possesses the multi-functional Germacrene D synthase activity, specifically the capability to convert farnesyl diphosphate to a mixture of Germacrene D and one or more other sesquiterpenes *in vitro*.

2. Election of Applicant's invention(s) was made without traverse. Because Applicant did not distinctly and specifically point out the supposed errors in the Group or species restriction requirement, the election has been treated as an election without traverse and the restriction and election requirement is deemed proper and therefore made final (MPEP § 818).

3. Claims 13-18, 24-27 and 29-44 are pending but withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention, there being no allowable generic or linking claim.

4. Claims 1-12, 19-23 and 28 are under consideration.

Priority

5. This application is a 371 of PCT/NZ03/00294, filed December 24, 2003. Acknowledgment is made of Applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d) of

the prior-filed application NZ/523384, filed on December 24, 2002. A certified copy of NZ/523384 has been filed with the instant application.

Information Disclosure Statement

Applicant has filed Information Disclosure Statements on November 2, 2006 that has been considered. The signed and initialed PTO Forms 1449 are mailed with this action.

Claim Objections

6. **Claims 3, 7 and 20 are objected to because of the following informalities:**

With respect to Claim 3, the claim identifies FDP as a substrate composition that is to be acted upon by the polypeptide of SEQ ID NO:2. However, the claim does not first identify the substrate composition by its complete name prior to using its acronym. The abbreviation should be spelled out in the first appearance of the claims and should be followed by the abbreviation in parentheses, e.g. Epidermal Growth Factor (EGF).

With respect to Claim 7, the claim is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to Claim 20, the claim is objected to because it depends from a claim withdrawn from examination.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. **Claims 1-6, 8-12, 19-23 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.** The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a polynucleotide encoding a polypeptide having Germacrene D synthase activity, wherein said polynucleotide was obtained from *Actinidia deliciosa*. At issue for the purpose of written description requirements, is the breadth of the claimed sequence identity of polynucleotide fragments or variants of SEQ ID NO:1, as compared to the polynucleotide of SEQ ID NO:1, such that the claimed fragment or variant polynucleotides will encode polypeptides having Germacrene D synthase activity.

> *Vas-cath Inc. v. Mahurkar*, 19USPQ2d 1111, clearly states that Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not clearly allow persons of ordinary skill in the art to recognize that (he or she) invented what is claimed." (See *Vas-cath* at page 1116).

In analyzing whether the written description requirement is met for genus claims, it is first determined whether a representative number of species have been described by their complete structure. In the instant case, EST 75565 having the nucleotide sequence of SEQ ID NO:1 is the only species whose complete structure is disclosed and demonstrated to encode a polypeptide having Germacrene D synthase activity (pg 35).

Next, then, it is determined whether a representative number of species have been sufficiently described by other relevant identifying characteristics (i.e. other than nucleotide sequence), specific features and functional attributes that would distinguish different members of the claimed genus. In the instant case, the only other identifying characteristic is that the

polynucleotide encode a polypeptide having Germacrene D synthase activity. The specification discloses that Bohlmann et al (Proc. Natl. Acad. Sci. USA 95, 4126-4133, 1998; *of record in IDS) compared the amino acid sequences of 33 terpene synthases and showed that there were seven absolutely conserved amino acid residues, that six positions were absolutely conserved for aromatic amino acids and four positions were absolutely conserved for acidic amino acids. Other regions of identity between synthases include four amino acids from amino acid 167 to 170 and four amino acids from amino acid 265 to 268 (pgs 29-30, joining ¶). For example, Germacrene D synthase contains a DDDXX(D,E) motif (specifically DDIYD) at amino acids 317 to 321 which is involved in the binding of divalent metal ions necessary for catalysis. Germacrene D synthase has a requirement for Mg2+ as a cofactor for activity and inhibition by Mn2+ ions. Mn can act as a cofactor when alone, but inhibits Mg-requiring cofactor activity (pg 45, lines 24-26). Germacrene D synthase was also shown to contain the angiosperm sequiterpene consensus sequence GVYXEP (GVYFEP) from amino acids 292-297 (pg 29, lines 23-29).

Applicant claims a broad genus of polynucleotides having at least 60% sequence identity to the polynucleotide sequence of SEQ ID NO:1, wherein the polynucleotide encodes a polypeptide having at least 60% sequence identity to the amino acid sequence of SEQ ID NO:2 and has Germacrene D synthase activity. However, the specification does not disclose any identifying characteristic as to how an artisan would have differentiated a Germacrene D synthase from one species from any other Germacrene D synthase. For example, the specification discloses that putative terpene synthase cDNA sequences were identified by their similarity to known terpene synthases based on key protein motifs (pg 28, lines 22-24) that are not disclosed. The specification also discloses a variant polynucleotide of SEQ ID NO:1, EST 72838, that does not contain the GVYFEP or DDIDY motifs (pg 30, lines 13-17) necessary for catalysis. It is noted that the disclosed polynucleotide variants have not been confirmed to encode the claimed enzymatic activity. It is noted that Applicant contemplates the term "variants" is used in recognition that it is possible to vary the amino acid/nucleotide sequence of a polypeptide/polynucleotide while retaining substantially equivalent functionality (pg 13, lines 20-22), particularly that homologs of SEQ ID NO:2 exist in other plants, wherein such homologs are also "variants" as the phrase is used herein (pg 18, lines 4-5). **In regard to polynucleotides from species other than *Actinidia deliciosa*, it is noted that the specification does not**

provide any disclosure whether these sequences from other species would have had the same characteristics or would have had additional characteristics or properties. It is noted that all these polynucleotides vary greatly in structure and function and therefore each represents a subgenus. Again, the members of any of the subgenuses themselves would have very different structure and the specification does not provide any description of any identifying characteristics of the species of the subgenuses.

The Revised Interim Guidelines state:

"The claimed invention as a whole may not be adequately described if the claims require an essential or critical element which is not adequately described in the specification and which is not conventional in the art" (col. 3, page 71434), "when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus", "in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (col. 2, page 71436).

An Applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

Possession may also be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the Applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 1 19 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998), *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997)*, *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200,

1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it").

Therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. See *Fiers v. Revel*, 25 USPQ2d 1602 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. *In Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

The Applicant has not provided any description or reduction to practice of the enormous genus of polynucleotides encoding a polypeptide having Germacrene D synthase activity besides the polynucleotide of SEQ ID NO:1 encoding the polypeptide of SEQ ID NO:2. Based on the Applicant's specification, the skilled artisan cannot envision the detailed chemical structure of the broad genus of nucleotide sequences encoding Germacrene D synthase activity as defined by the specification and encompassed by the claims. The one species of agent specifically disclosed, SEQ ID NO:1, is not representative of the genus because the genus is highly variant. Accordingly, this limited information is not deemed sufficient to reasonably convey to one skilled in the art that the Applicant is in possession of the broad genus of polynucleotides, besides SEQ ID NO:1, at the time the application was filed.

Thus, for the reasons outlined above, it is concluded that the claims do not meet the requirements for written description under 35 U.S.C. 112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

8. **Claims 1-6, 8-12, 19-23 and 28 are rejected under 35 U.S.C. 112, first paragraph,** because the specification, while being enabling for a polynucleotide of SEQ ID NO:1 encoding a polypeptide of SEQ ID NO:2 having multi-functional Germacrene D synthase activity, does not

reasonably provide enablement for an enormous genus of fragments or variants of the polynucleotide of SEQ ID NO:1 to also encode a polypeptide having multi-functional Germacrene D synthase activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

While determining whether a specification is enabling, one considers whether the claimed invention provides sufficient guidance to make and use the claimed invention. If not, whether an artisan would have required undue experimentation to make and use the claimed invention and whether working examples have been provided. When determining whether a specification meets the enablement requirements, some of the factors that need to be analyzed are: the breadth of the claims, the nature of the invention, the state of the prior art, the level of one of ordinary skill, the level of predictability in the art, the amount of direction provided by the inventor, the existence of working examples, and whether the quantity of any necessary experimentation to make or use the invention based on the content of the disclosure is "undue" (*In re Wands*, 858 F.2d 731, 737, 8 USPQ2ds 1400, 1404 (Fed. Cir. 1988)). Furthermore, USPTO does not have laboratory facilities to test if an invention will function as claimed when working examples are not disclosed in the specification. Therefore, enablement issues are raised and discussed based on the state of knowledge pertinent to an art at the time of the invention. And thus, skepticism raised in the enablement rejections are those raised in the art by artisans of expertise.

The Breadth of the Claims and The Nature of the Invention

The breadth of the claims is exceptionally large for embracing an enormous genus of structurally diverse polynucleotides having the desired enzymatic activity of multi-functional Germacrene D synthase activity, wherein such polynucleotides may be integrated into an enormous genus of genetic constructs comprising an enormous genus of promoter sequences and termination sequences.

The inventive concept in the instant application is the identification of a polynucleotide, EST 75565 having the nucleotide sequence of SEQ ID NO:1, from *Actinidia deliciosa*, wherein said polynucleotide encodes a Germacrene-D synthase of SEQ ID NO:2, that when purified, is capable of converting farnesyl diphosphate to a mixture of Germacrene-D and one or more other

sesquiterpenes, specifically delta-cadinene, delta-elemene, elemol, gamma-muurolene, gamma-cadinene, gamma-elemene and Germacrene-B *in vitro* (pgs 35-36).

The State of the Prior Art, The Level of One of Ordinary Skill and The Level of Predictability in the Art

The claims are drawn to polynucleotides encoding plant terpenoid synthase enzymes, wherein the level of one of ordinary skill is considered to be high.

The art teaches that terpene synthases are proteins of 550 to 850 amino acids represented by six distantly related subfamilies, *Tpsa*, *Tpsb*, *Tpsc, Tpsd, Tpse* and *Tpsf*, wherein *Tpsa* represents the Germacrene-D/δ-cadinene synthase subfamily (Bohlmann et al, Proc. Natl. Acad. Sci. USA 95, 4126-4133, 1998; *of record in IDS; pg 4129, Figure 5). Bohlmann et al also teach that terpenoid synthases of subfamilies Tpsa, Tpsb and Tpsd show much greater functional diversity than do members of the other Tpsc group (pg 4130, col. 1, ¶1). It appears that terpene synthases of subfamilies *Tpsa*, *Tpsb,* and *Tpsd* are composed of two distinct structural domains, a C-terminal active site domain, and an N-terminal domain that structurally resembles catalytic cores of glycosyl hydrolysases (pg 4130, col. 2, ¶1). Comparison of 28 terpene synthases of the *Tpsa, Tpsb* and *Tpsd* subfamilies reveals seven absolutely conserved amino acid residues, six positions absolutely conserved for aromatic amino acids, and four positions absolutely conserved for acidic amino acids. Very few of the residues that are absolutely conserved among synthases of the *Tpsa*, *Tpsb*, and *Tpsd* subfamilies are also conserved in distantly related synthases of subfamilies *Tpsf*, *Tpse*, and *Tpsc* (pg 4130, col. 2, Specific Structural Elements; pg 4131, Figure 6).

Given that only 17 amino acid positions of the 550 to 850 amino acids known to exist in terpenoid synthases, at most 3% of the known amino acid sequences, are of near absolute conservation, one of ordinary skill in the art would reasonably recognize considerable uncertainty regarding which amino acids may be altered *a priori* so as to retain the claimed enzymatic activity. Although highly conserved structural elements likely are involved in general cyclization reaction chemistry (ionization, charge stabilization, deprotonation), it is the differences in active-site size and shape that enforce conformation on substrates and intermediates to direct the selectivity of this group of fascinating catalysts. Comparative

investigations of closely related synthases should target those structural features that determine the basic modes of cyclization and that underlie regiochemical and stereochemical diversity so characteristic of this enzyme family. Comparison of highly specific synthases with those that produce an assortment of products can identify structural determinants of fidelity, or the lack thereof (pg 4132, col. 2, Perspective). Thus, the amino acids necessary to convert farnesyl diphosphate into the sub-genus of compounds embraced by the claims, specifically delta-cadinene, delta-elemene, elemol, gamma-muurolene, gamma-cadinene, gamma-elemene and Germacrene-B, by the polypeptide of SEQ ID NO:2 cannot be predicted *a priori*.

The Existence of Working Examples and The Amount of Direction Provided by the Inventor

The specification discloses that the instant polynucleotide of SEQ ID NO:1 was identified as a putative terpene synthase by it similarity to known terpene synthases based on key protein motifs (pg 28, lines 22-24), wherein the specific motifs are not disclosed. Other regions of identity between synthases include four amino acids from amino acid 167 to 170 and four amino acids from amino acid 265 to 268 (pgs 29-30, joining ¶). For example, Germacrene D synthase contains a DDDXX(D,E) motif (specifically DDIYD) at amino acids 317 to 321 which is involved in the binding of divalent metal ions necessary for catalysis. Germacrene D synthase has a requirement for Mg2+ as a cofactor for activity and inhibition by Mn2+ ions. Mn can act as a cofactor when alone, but inhibits Mg-requiring cofactor activity (pg 45, lines 24-26). Germacrene D synthase was also shown to contain the angiosperm sequiterpene consensus sequence GVYXEP (GVYFEP) from amino acids 292-297 (pg 29, lines 23-29).

The specification also discloses a variant polynucleotides of SEQ ID NO:1. For example, EST 72838 does not contain the GVYFEP or DDIDY motifs (pg 30, lines 13-17) necessary for catalysis. It is noted that the disclosed polynucleotide variants have not been confirmed to encode the claimed enzymatic activity. Besides these few amino acids, the specification fails to disclose those amino acid residues that are necessary to retain the claimed enzymatic activity.

The Quantity of Any Necessary Experimentation to Make or Use the Invention

Thus, the quantity of necessary experimentation to make or use the invention as claimed, based upon what is known in the art and what has been disclosed in the specification, will create

an undue burden for a person of ordinary skill in the art to demonstrate that the enormous genus of fragments and variants of the polynucleotide of SEQ ID NO:1 will encode a polypeptide having multi-functional Germacrene D synthase activity.

For example, while methods of isolating or generating variants of a polypeptide were known in the art at the time of the invention, it was not routine in the art to screen - by a trial and error process - for all polypeptide variants having a substantial number of modifications as encompassed by the claims for those polypeptides having the desired activity/utility. Guo et al. (Proc Natl Acad Sci 101(25):9205-9210, 2004) teach a study suggesting that the percentage of variants having multiple substitutions that maintain activity appears to be exponentially related by the simple formula: $(.66)^x$ X 100% (where x is the number of mutations introduced). Looking at the most limited of the variant claims (Claim 6) wherein the polynucleotide is limited to a polynucleotide having at least 95% identity to SEQ ID NO:l, the polynucleotide can have 5% of the nucleotides altered. Thus, up to 101 nucleotides within the 2019 nucleotides of SEQ ID NO:1 can be simultaneously mutated. According to Guo et al., only 5.9×10^{-17}% of random mutants having 95% identity to SEQ ID NO:1 would be encode a polypeptide having the desired, and claimed, and claimed activity. Similarly, the most limited of the variant claims (Claim 11) wherein the polypeptide is limited to a polypeptide having at least 95% identity to SEQ ID NO:2, only $(.66)^{28}$ X 100% or 8.9×10^{-4}% of random mutants having 95% identity to SEQ ID NO:2 would be active. Thus, a significant number of variants must be screened in order to isolate those variants of SEQ ID NO:1 having the desired activity to convert farnesyl diphosphate into the sub-genus of compounds embraced by the claims, specifically delta-cadinene, delta-elemene, elemol, gamma-muurolene, gamma-cadinene, gamma-elemene and Germacrene-B. The art clearly does not typically engage in the screening of such a large number of variants to isolate those relatively few variants that would have the desired activity/utility. That screening this number of variants is not routinely practiced in the art is evidenced by Hult and Berglund (Curr Opin Biotechnol 14:395-400, 2003), which teaches that recent attempts to randomly obtain variants of a given polypeptide included screening of "6000 transformants" (p. 396, left column, top) or 3.4×10^7 variants (p. 396, left column, bottom).

In conclusion, the specification fails to provide any guidance as to how an artisan would have dealt with the art-recognized limitations of the claimed method commensurate with the

scope of the claimed invention and therefore, limiting the claimed invention to a polynucleotide of SEQ ID NO:1 encoding a polypeptide of SEQ ID NO:2 having multi-functional Germacrene D synthase activity, is proper.

Conclusion

9. No claims are allowed

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The Examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Joseph T. Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kevin K. Hill

Q. JANICE LI, M.D.
PRIMARY EXAMINER